

State of California
M e m o r a n d u m

HSM-96006

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To: Gary Patterson, Supervising Toxicologist
Medical Toxicology Branch

Date: January 26, 1996
Place: Sacramento

From: **Department of Pesticide Regulation** - John M. Donahue, Chief
Worker Health and Safety Branch

Subject: Parameters Defining Insignificant Exposure

The Department has been asked several times recently to exempt and/or waive SB 950 studies based on insignificant exposure. We have been asked before and will continue to be queried from within the Department as well as from "the public" about what constitutes insignificant exposure. The answer has always been subjective because there are so many variables affecting exposure. However, I think we can construct some generic limits with regard to magnitude, frequency and duration of exposure that would be targets for in significant exposure. Some excellent examples of what constitutes significant exposure can be found in the footnotes of 40 CF R 158.340. Based on that guidance and our own experience with risk assessment, we might construct a table as shown below:

Table 1: Insignificant Exposure Indices

<u>Magnitude</u>	<u>Frequency</u>	<u>Duration</u>
<0.3 µg/kg/day	<40 days/yr	<10 yr/75 yr lifetime

The Absorbed Daily Dosage (ADD) of <0.3 µg/kg/day would be applicable to effects such as teratology that can take place following a single exposure. A Lifetime Average Daily Dosage (LADD) under these conditions would be 0.0044 µg/kg. Using this definition for insignificant exposure, unless a pesticide were extremely potent chronically [i.e., $Q^* > 2(\text{mg/kg/day})^{-1}$ or $\text{NOEL} < 0.4 \text{ µg/kg}$] it would not produce significant risk. We are not aware of any currently registered pesticide with cancer potency this high

Such a definition of insignificant exposure would encourage registrants to expend resources defining worker exposure through new monitoring studies, dermal absorption studies conducted in the species of choice (man) and work time surveys because these studies are extremely cost effective relative to conducting lifetime toxicology studies in laboratory animals. This definition does not preclude risk assessments for acute or subchronic exposure toxicology endpoints.

We conducted a survey of all the exposure assessments at or near completion and summarized the range of ADD and LADD for each active ingredient (Table 2). It is clear from this summary that



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there are very few, if any, high priority SB pesticides that would produce either acute or lifetime exposure of sufficiently low exposure to be considered insignificant by the proposed criteria.

None of these insignificant exposure criteria numbers should be considered bright lines below which an exposure must fall to be considered insignificant, because there are a number of other factors that may influence exposure which have not been included. However, these "targets" for ADD and LADD would be a reference for anyone contemplating a petition for insignificant exposure, and a starting point for any regulatory justification of insignificant exposure.

cc: Keith Pfeifer
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Table 2
**Ranges of Average Absorbed Daily Dose and Lifetime Absorbed Daily Dose
For Various Pesticides From Occupational Exposure^(a)**

ADD: Absorbed Daily Dose (µg/kg/day)

LADD: Lifetime Absorbed Daily Dose (µg/kg/day)

Active Ingredient	HS Report	APPLICATION WORK TASKS ^(b,c) (handlers) ^(d)		FIELD TASKS (reentry tasks) ^(e)	
		ADD	LADD ^(f)	ADD	LADD ^(f)
1. Abamectin	1567	0.025-0.11	-----	0.0005-0.011	-----
2. Alachlor	1465	15.6	25.5	-----	-----
3. Aldicarb	1602	0.03-74.3	-----	-----	-----
4. Amitraz	1529	0.51-25.7	0.0048-0.37	36.9	1.94
5. Amitrole	1470	5.5-69	0.7-9.0	-----	-----
6. Atrazine	1636	0.07-289	0.003-30.6	-----	-----
7. Azinphos-methyl	1650	14.4-68.5	0.30-1.01	2.2-85.6	0.27-10.9
8. Benomyl	1557	8.57-719	0.4-33.8	4.93-60.2	0.20-2.2
9. Bensulfuron-methyl ^(g)	-----	48	15.45	-----	-----
10. Bifenthrin	1561	0.09-29.7	0.005-1.86	5.86	0.37
11. Bromoxynil	1467	6.57-13.14	-----	-----	-----
12. Captafol	1471	4.6-14.5	0.22-0.55	6.0-30.8	0.84-3.37

Active Ingredient	HS Report	APPLICATION WORK TASKS ^(b,c) (handlers) ^(d)		FIELD TASKS (reentry tasks) ^(e)	
		ADD	LADD ^(f)	ADD	LADD ^(f)
13. Captan	1468	211-1633	20.1-153.5	35.2-215	4.8-23.3
14. Chlorothalonil	1475	2.34-596	0.10-69.7	0.15-33.5	0.0003-3.70
15. Chlorpyrifos	1661	0.33-342	0.086-16.9	0.08-16.2	0.029-1.23
16. Cyanazine	1526	5.71-1871	-----	-----	-----
17. Cycloate	1556	242-408	-----	-----	-----
18. Cyhexatin	1478	9.12-1825	2.0-86.0	-----	-----
19. Cyromazine	1645	9.25-37.8	0.15-0.60	ND-1.4	-----
20. Daminozide	1520	68.6-1257	24.6-379	-----	-----
21. DDVP	1540	9.0-62.0	0.40-2.6	12.0	0.30
22. Diazinon ^(h)	1694	-----	-----	0.01-0.4	-----
23. Dichloropropene	1634	6.8	-----	-----	-----
24. Diflubenzuron	1473	28.6-1786	-----	-----	-----
25. Dinocap	1469	27.9-359	2.62-33.7	27.9-57.8	1.75-3.62
26. Diquat dibromide	1662	0.3-106	0.005-2.49	-----	-----
27. EPTC	1531	66.9-89.8	1.0-1.4	-----	-----
28. Ethoprop	1628	15-49	0.5-0.7	-----	-----
29. Fenoxaprop-ethyl	1695	1.0-44	0.15-10.13	-----	-----
30. Fenpropathrin	1684	0.8-24.04	0.03-1.51	0.35-29.74	0.12-10.2

Active Ingredient	HS Report	APPLICATION WORK TASKS ^(b,c) (handlers) ^(d)		FIELD TASKS (reentry tasks) ^(e)	
		ADD	LADD ^(f)	ADD	LADD ^(f)
31. Fenthion	1599	120-420	-----	-----	-----
32. Flucythrinate	1510	9,542-67,316	105-738	62.6-5996	35.8-3426
33. Flutolanil	1579	12.9-1	28.6-3086	-----	-----
34. Folpet	1464	1697-4429	160-416	140-1460	26-274
35. Hydrogen cyanamide	1685	2.6±0.5 - 11.6±4.7	0.69-3.09	-----	-----
36. Imidacloprid	1682	2.3-14.34	0.68-4.25	39.8	11.79
37. Isofenphos	1559	13-61	3-14	-----	-----
38. Malathion	1569	0.006-0.70	-----	-----	-----
39. Mancozeb	1525	12.4-491	0.67-3.74		0.73-2.45
40. Mevinphos	1653	0.8-2.4	-----	0.4-12.0	-----
41. Molinate	1543	2.4-201	0.10-8.50	-----	-----
42. Monocrotophos	1472	9-21	1.4-2.1	173	10.8
43. Myclobutanil ^(g)	-----	0.2-0.6	0.01-0.04	7-26	0.06-2.3
44. Oxydemeton-methyl	1536	4.3-246	0.29-15.4	0.87-15.9	0.17-3.03
45. Paclobutrazol	1606	11	0.63	0.0065	0.0024
46. Paraquat	1560	0.49-84.5	0.02-3.97	1.33	0.06
47. Pentachlorophenol	1596	2.0-6.2	0.1-2.9	-----	-----
48. Permethrin	1582	-----	-----	4.2	1.2

Active Ingredient	HS Report	APPLICATION WORK TASKS ^(b,c) (handlers) ^(d)		FIELD TASKS (reentry tasks ^(e))	
		ADD	LADD ^(f)	ADD	LADD ^(f)
49. Phosmet	1476	-----	-----	88-1374	14-65
50. Propargite	1527	41-264	-----	8-26 ^(h)	-----
51. Propiconazole	1605	11.5-23.8	-----	-----	-----
52. Propoxur	1655	6.7-23.9	0.50-2.0	-----	-----
53. Sodium tetrathiocarbonate	<i>memo</i>	parent: 0.15 gas (CS ₂): 2.2	-----	-----	-----
54. Triadimefon	1572	176-1343	5.47-low only	-----	-----
55. Triadimenol	1614	0.29-2.43	0.004-0.04	-----	-----

(a) Occupational exposure estimates made with the worker wearing the protective clothing required by the product label.

(b) When the HS Report listed the exposure from the mixing/loading and application work tasks separately, the listed value represents the sum of the two, except for aerial application.

(c) The rate of dermal absorption was assumed to be 100% in the absence of data.

(d) Handler as defined in CCR section 6000.4 (g).

(e) Refer to human tasks that involve such activities as scouting, harvesting, pruning, culling/sorting/grading, etc of agriculture commodities post pesticide treatment(s).

(f) Calculated with 40 years of exposure over a 70 year lifespan except when otherwise noted.

(g) From Risk Characterization Document.

(h) Exposure study on residential turf & soil. Range based on 9 kg child. Simulated data not cited.